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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/596,753

06/22/2006

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Q95486

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23373 7590 11/24/2009
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EXAMINER

BADR, HAMID R

ART UNIT

PAPER NUMBER

1794

NOTIFICATION DATE

DELIVERY MODE

11/24/2009

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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DETAILED ACTION

Applicants' amendment filed 9/14/2009 is acknowledged.

Claim rejections under 35 U.S.C. 112 first and second paragraphs are withdrawn due to claim cancellations.

Claims 10 and 15 are being considered on the merits.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 10 and 15 are rejected under 35 U.S.C. 102(b) as being anticipated by Yamamoto et al. (JP 11-098978 , Machine Translation; hereinafter R1).

3. R1 discloses a fermented milk product produced by lactic acid bacteria and containing large amount of tripeptides such as Val-Pro-Pro and Ile-Pro-Pro. The lactic acid bacteria used are *Lactobacillus helveticus* CM4 (FERM BP-6060 (page 1, claims 1 and 2 and page 12, paragraph 0055)). This is the same strain as presently claimed.

4. R1 discloses that milk of various sources and the skim milk can be used for the fermentation process. (page 6, paragraph 0029).

5. R1 discloses the type of products which can contain the tripeptides as yogurt, beverage, cheese, sour milk, health food, powder, tablets etc. (page 6, paragraph 0032, 0035)

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6. It is noted that the moisturizing effect and filaggrin synthesis promoting effect of the fermented product is not mentioned by R1, however, the raw material, the specific strain, and the fermentation conditions as disclosed by R1 are identical to the raw materials, the specific strain and the fermentation conditions as presently disclosed, therefore, any resulting moisturizing effect and filaggrin synthesis promoting effect of the fermented product be inherent in the fermented products when these products are orally administered.

7. The fermented milk, using CM4 strain, as disclosed by R1 will contain the fermented whey and the active compounds e.g. active tripeptides. When this product is orally administered to a subject, whether the subject has normal skin or dry skin, the active components will affect the subject, therefore the effect will be inherent in the product.

8. R1 further discloses that the concentration of Val-Pro-Pro in the whey of the sample fermented by the CM4 strain is highest compared to other strains. (page 10, paragraph 0048 and Table 2)

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claims 10 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over JP H10-045610 (Machine translation, hereinafter R2).

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11. R2 discloses fermented milk products such sour milk wherein *Lactobacillus helveticus* has been used as the lactic acid bacteria. (page 1, claims 1-4).

12. R2 discloses the milk raw material sources as regular milk, full fat milk, skim milk, whey, defatted milk. (page 3, paragraph 0009)

13. R2 discloses other lactic acid bacteria which may be used for that purpose. Among the lactic acid bacteria disclosed by R2, *Lactobacillus helveticus* ATCC-55796 is the preferred organism. (page 3, paragraph 0012)

14. R2 discloses that food such as yogurt, beverages, cheese, health foods and powders may be used as functional foods of the invention. (page 5, paragraph 0019)

15. R2 does not mention moisturizing and fillaggrin synthesis promoting effects of the fermented product as presently claimed, however, since *Lactobacillus helveticus*, the raw materials and the fermentation conditions as disclosed by R2 are similar to the lactic acid bacterium (*Lactobacillus helveticus*), the raw materials and the fermentation conditions as presently claimed, the moisturizing and filaggrin synthesizing effects of the fermented products will be intrinsic when such products are administered orally to subjects having dry skin.

16. Since R2 discloses the raw materials for the fermentation and it also uses the lactic acid bacteria as presently claimed, it would have been obvious to one of ordinary skill in the art to ferment milk and milk products such as whey to produce fermented milk products which could be orally administered. The moisturizing and filaggrin synthesizing effects, as presently claimed, would have been intrinsic in these products when administered orally. Absent any evidence to contrary and based on the teachings of the

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cited reference, there would be a reasonable expectation of success in making such fermented products.

Response to Arguments

1. Applicants argue that R1 does not teach that fermented milk whey obtained by fermentation of milk with *Lactobacillus helveticus* has a skin moisturizing effect.

a. When milk is fermented using *Lactobacillus helveticus* CM-4 as the fermentative organism, under the conditions taught by R1, it will include all active components. Since the process, the raw material and the lactobacillus strain as presently claimed are identical to the those disclosed by R1, it is clear that active components, having the moisturizing effect, will be identical to those components as disclosed by R1.

Therefore, when the fermented product of R1 is administered to a person of normal or dry skin the physiological effect of the disclosed product by R1 and the product as presently claimed would be identical. The moisturizing effect of the fermented product will be inherent in the product as disclosed by R1.

2. Applicants argue that R2 does not teach or suggest that fermented milk whey obtained by fermentation of milk with *Lactobacillus helveticus* has a skin moisturizing effect.

a. R2 is using a specific strain of *Lactobacillus helveticus* in fermenting milk products under conditions as presently claimed. Therefore, the active components in the fermented product of R1 will intrinsically contain the active components having moisturizing effect as presently claimed. The moisturizing effect of the product as

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disclosed by R1 and as presently claimed would be identical when such products are orally administered to subjects having normal skin or dry skin.

3. Applicants have submitted an attachment for Examiner's consideration.

Additionally the Applicants argue that ingesting the fermented milk whey of the present invention by a subject having dry skin would not be analogous to ingesting by a person having normal skin.

a. The attachment provided by the applicants has been considered. The attachment does not appear to be relevant to the instant claim language, therefore it is not persuasive. Further, the fermented products of R1 and R2 contain the same active compounds as presently claimed, because the bacterial strain, the raw materials and the fermentation conditions, as presently claimed, are the same as those disclosed by R1 and R2. Therefore, it is logical to state that when orally administered, the moisturizing effect of such products would be the same.

Conclusion

17. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. WO 2000/41572, JP 10-95736, JP 2000-239175. All of these documents disclose fermented milk products using *Lactobacillus helveticus*. They also disclose that such fermented products can be used in functional foods, dietary supplements etc.

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18. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to HAMID R. BADR whose telephone number is (571)270-3455. The examiner can normally be reached on M-F, 8:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Keith Hendricks can be reached on (571) 272-1401. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Hamid R Badr
Examiner
Art Unit 1794

/Keith D. Hendricks/

Supervisory Patent Examiner, Art Unit 1794